Notice of Allowability	Application No.	Applicant(s)	
	10/715,795	STEWART ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment filed 27 July 2005*.

2. ☒ The allowed claim(s) is/are *1-8,14-21,25-27,34-36 and 46*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 04/01/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 July 2005 has been entered.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Cara Coburn on October 19, 2005.

A complete claim set incorporating all of the changes discussed with Applicant's representative follow. To summarize, claims 9-10, 24, and 37-45 were cancelled, claims 1, 5, and 7 were amended to recite 95% sequence identity and claims 35 and 46 were amended to reflect proper claim dependency. Claim 27 was rewritten to convey clarity of the encoded polypeptide.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1 (currently amended): An isolated nucleic acid molecule comprising a polynucleotide having at least about ~~90%~~ 95% sequence identity to a DNA molecule encoding an FGF-19 polypeptide comprising amino acid residues from 1 or 23 to 216 of Figure 2 (SEQ ID NO:2), wherein the FGF-19 polypeptide reduces total body mass in an individual, reduces fat in an individual, reduces the level of triglycerides and free fatty acids in an individual, increases metabolic rate of an individual, induces leptin release from an adipocyte cell, or decreases glucose uptake in an adipocyte cell.

2 (previously presented): The isolated nucleic acid molecule of Claim 1 comprising nucleotides from 464 or 530 to 1111 of Figure 1 (SEQ ID NO:1).

3 (previously presented): The isolated nucleic acid molecule of Claim 1 comprising the polynucleotide sequence of Figure 1 (SEQ ID NO: 1).

4 (previously presented): The isolated nucleic acid molecule of Claim 1 comprising a polynucleotide sequence that encodes amino acid residues from 1 or 23 to 216 of Figure 2 (SEQ ID NO:2).

5 (currently amended): An isolated nucleic acid molecule comprising a polynucleotide having at least about ~~90%~~ 95% sequence identity to a DNA molecule encoding the same mature polypeptide encoded by the human protein cDNA deposited with the ATCC on November 21, 1997 under ATCC Deposit No. 209480 (DNA49435-1219), wherein the mature polypeptide reduces total body mass in an individual, reduces fat in an individual, reduces the level of triglycerides and free fatty acids in an individual, increases metabolic rate of an individual, induces leptin release from an adipocyte cell, or decreases glucose uptake in an adipocyte cell.

6 (previously presented): The isolated nucleic acid molecule of Claim 5 comprising a polynucleotide encoding the same mature polypeptide encoded by the human protein cDNA deposited with the ATCC on November 21, 1997 under ATCC Deposit No. 209480 (DNA49435-1219).

7 (currently amended): An isolated nucleic acid molecule comprising a polynucleotide having at least about ~~90%~~ 95% sequence identity to the full-length polypeptide coding sequence of the human protein cDNA deposited with the ATCC on November 21, 1997 under ATCC Deposit No. 209480 (DNA49435-1219), wherein the polypeptide encoded by the human protein cDNA reduces total body mass in an individual, reduces fat in an individual, reduces the level of triglycerides and free fatty acids in an individual, increases metabolic rate of an individual, induces leptin release from an adipocyte cell, or decreases glucose uptake in an adipocyte cell.

8 (original): The isolated nucleic acid molecule of Claim 7 comprising the full-length polypeptide coding sequence of the human protein cDNA deposited with the ATCC on November 21, 1997 under ATCC Deposit No. 209480 (DNA49435-1219).

9 -13 (canceled)

14 (previously amended): A vector comprising the nucleic acid molecule of any of Claims 1, 4, 5, or 6.

15 (original): The vector of Claim 14, wherein said nucleic acid molecule is operably linked to control sequences recognized by a host cell transformed with the vector.

16 (original): A nucleic acid molecule deposited with the ATCC under accession number 209480 (DNA49435-1219).

17 (original): A host cell comprising the vector of Claim 14.

18 (original): The host cell of Claim 17, wherein said cell is a CHO cell.

19 (original): The host cell of Claim 17, wherein said cell is an *E. coli*.

20 (original): The host cell of Claim 17, wherein said cell is a yeast cell.

21 (original): A process for producing an FGF-19 polypeptide comprising culturing the host cell of Claim 17 under conditions suitable for expression of said FGF-19 polypeptide and recovering said FGF-19 polypeptide from the cell culture.

22-24 (cancelled)

25 (previously amended): The isolated nucleic acid of Claim 1, wherein the polynucleotide has at least about 99% sequence identity to (a) a DNA molecule encoding an FGF-19 polypeptide comprising amino acid residues from 1 or 23 to 216 of Figure 2 (SEQ ID NO:2), or (b) the complement of the DNA molecule of (a).

26 (previously amended): The isolated nucleic acid molecule of Claim 1 consisting of a polynucleotide sequence that encodes amino acid residues from 1 or 23 to 216 of Figure 2 (SEQ ID NO:2).

27 (currently amended): The isolated nucleic acid molecule of Claim 1 comprising a polynucleotide sequence that encodes ~~amino acid residues from any of 17 to 27 to 216 of Figure 2 (SEQ ID NO:2)~~ a polypeptide having a portion of the amino acid sequence of Figure 2 (SEQ ID NO:2), wherein the N-terminus begins with any of amino acid residues 17 to 27 and wherein the C-terminus is amino acid residue 216.

28-33 (cancelled)

34 (previously presented): A process for producing an FGF-19 polypeptide comprising culturing a host cell comprising a nucleic acid molecule deposited with the ATCC under accession number 209480 (DNA49435-1219) under conditions suitable for expression of said FGF-19 polypeptide and recovering said FGF-19 polypeptide from the cell culture.

35 (currently amended): A composition comprising the polynucleotide of any of Claims ~~1, 4, 5, 7, or 9~~ 1, 4, 5, or 7.

36 (previously presented): The host cell of Claim 17, wherein said cell is a mammalian cell.

37- 45 (cancelled)

46 (currently amended): An isolated nucleic acid encoding a chimeric molecule, wherein the isolated nucleic acid comprising (a) a nucleic acid of any of claims ~~1, 5, 7, 9. or 37,~~ 1, 5, or 7, fused to (b) a polynucleotide encoding a heterologous polypeptide.

The following is an examiner's statement of reasons for allowance: the invention of the instant application is directed to polynucleotides encoding FGF-19. The closest art is Nishimura et al. (Biochimica et Biophysica acta 1444(1): 148-151, January 18, 1999). Nishimura et al. teach FGF-19 (see Figure 1). The instant specification claims priority to earlier filed applications, including 09/158,342, which was filed September 21, 1998. The specification of the '342 application teaches the physical structure of FGF-19, protein and nucleic acid, and therefore, the instant specification is entitled benefit to the earlier filed applications for this subject matter. Therefore, the teachings of Nishimura et al. are not prior art against the claims in the instant application. See *In re Stempel*, 113 USPQ 77 (CCPA 1957).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud